# UNITED STATES PATENT AND TRADEMARK OFFICE

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/663,158 | 09/15/2003 | Frederic DeSauvage | 11669.123USC1 | 4053 |

23552    7590    03/22/2007

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| EXAMINER |
|---|
| SKELDING, ZACHARY S |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 31 DAYS | 03/22/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | Application No. | Applicant(s) |
|---|---|---|
| **Office Action Summary** | 10/663,158 | DESAUVAGE ET AL. |
| | Examiner | Art Unit | |
| | Zachary Skelding | 1644 | |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on <u>05 January 2007</u>.

2a) ☐ This action is **FINAL**.    2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) <u>1 and 35-68</u> is/are pending in the application.

    4a) Of the above claim(s) <u>1, 36-48, 51-56 and 60-68</u> is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claim(s) <u>35, 49, 50 and 57-59</u> are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All   b) ☐ Some * c) ☐ None of:

        1. ☐ Certified copies of the priority documents have been received.

        2. ☐ Certified copies of the priority documents have been received in Application No. _____.

        3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

## DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed September 27, 2006 has been entered.

2. Applicant's amendment to the claims, filed September 27, 2006, has been entered.

   Claims 35 has been amended.

   Claims 2-34 have been canceled.

   Claims 36-68 have been added.

   Claims 1 and 35-68 are pending.

   Claims 35, 49, 50 and 57-59 are under examination as they read on a method for inhibiting the differentiation of Th0 cells into a Th2 subtype comprising administering an anti-TCCR antibody agonist.

   Claims 1, 36-48, 51-56 and 60-68 are withdrawn as being drawn to a non-elected invention.

3. *Upon further consideration, the following supplemental species election is set forth as it reads on the elected invention.*

   *The Examiner apologizes for any inconvenience to applicant in this matter.*

### *Species Election*

5. This application contains claims generic to patentably distinct species of the claimed invention. Applicant is **required to elect if the claimed method comprises administration of:**

   A. an antibody that agonizes *murine* TCCR and variants thereof, such as SEQ ID NO: 1

   OR

   B. an antibody that agonizes *human* TCCR and variants thereof, such as SEQ ID NO: 2.

Related inventions are patentably distinct if the inventions *as claimed* are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art). See MPEP § 802.01.

In the instant case, the instantly claimed methods comprise administration of agonistic antibodies that bind patentably distinct antigens. The polypeptide antigens bound by the instantly claimed antibodies are structurally different in that they share just 62% identity across 618 amino acids with no appreciable identity at their N and C termini (see attached alignment).

Moreover, the physiochemical properties of these polypeptides are different, and/or they do not share a common structure that is disclosed to be essential for common utility, and in turn antibodies that recognize these polypeptides are patentably distinct. Indeed, one post-filing date anti-TCCR antibody generated using human TCCR polypeptide antigen, the 2686 antibody, recognizes, and appears to induce TCCR signaling in Ba/F3 cells; however the 2686 antibody does not bind/induce signaling of murine TCCR (see US20060177436, page 19, paragraph [0219], cited herewith).

Furthermore, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

*If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.*

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

6.  Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the
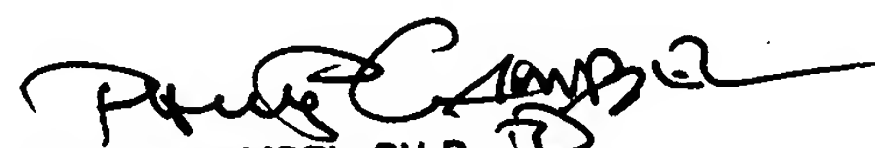
examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
March 19, 2007

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER

# NCBI Blast 2 Sequences results

## BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.15 [Oct-15-2006]

Matrix BLOSUM62 ▾ gap open: 11 gap extension: 1

x_dropoff: 50 expect: 10.000 wordsize: 3 Filter ☐ View option Standard ▾

Masking character option X for protein, n for nucleotide ▾ Masking color option Black ▾

☐ Show CDS translation   Align

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**Sequence 1**: lcl|1_sin2
Length = 623 (1 .. 623)

*MOUSE VS.*

**Sequence 2**: lcl|2_sin1
Length = 636 (1 .. 636)

*(HUMAN) TCCR*
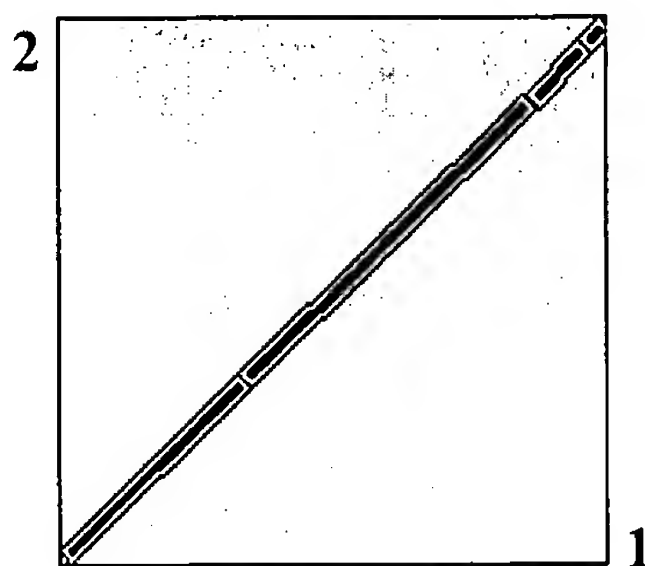
NOTE:Bitscore and expect value are calculated based on the size of the nr database.

```
 Score =  789 bits (2037),  Expect = 0.0
 Identities = 388/618 (62%),  Positives = 449/618 (72%),  Gaps = 8/618 (1%)

Query   9    LTPLELLLSLMSLLLGTRPHGSPGPLQCYSVGPLGILNCSWEPLGDLETPPVLYHQSQKY   68
             L  L LL  L  L    TRP GS GPLQCY VGPLG LNCSWEPLGDL  P  L+ QSQKY
Sbjct   14   LPKLALLPLLWVLFQRTRPQGSAGPLQCYGVGPLGDLNCSWEPLGDLGAPSELHLQSQKY   73

Query   69   HPNRVWEVKVPSKQSWVTIPREQFTMADKLLIWGTQKGRPLWSSVSVNLETQMKPDTPQI   128
             N+    V V + +SWV IPREQ TM+DKLL+WGT+ G+PLW  V VNLETQMKP+ P++
Sbjct   74   RSNKTQTVAVAAGRSWVAIPREQLTMSDKLLVWGTKAGQPLWPPVFVNLETQMKPNAPRL   133

Query   129  FSQVDISEEATLEATVQWAPPVWPPQKALTCQFRYKECQAEAWTRLEPQLKTDGLTPVEM   188
               VD SE+   LEATV WAPP WP  K L CQF Y+ CQ  AWT LEP+LKT   LTPVE+
Sbjct   134  GPDVDFSEDDPLEATVHWAPPTWPSHKVLICQFHYRRCQEAAWTLLEPELKTIPLTPVEI   193

Query   189  QNLEPGTCYQVSGRCQVENGYP-WGEWSSPLSFQTPFLDPEDWVSGTVCETSGKRAALL   247
             Q+LE  T Y+V GRC++E    WGEWS  LSFQTP   P+DWVSG +C T G    LL
Sbjct   194  QDLELATGYKVYGRCMEKEEDLWGEWSPILSFQTPPSAPKDVWVSGNLCGTPGGEEPLL   253

Query   248  VWKDPRPCVQVTYTVWFGAGDITTTQEEVPCCKSPVPAWMEWAVVSPGNSTSWVPPTNLS   307
             +WK P PCVQV+Y VWF G    + E + CC S +P+ EWA VS N+TSW P TNLS
Sbjct   254  LWKAPGPCVQVSYKVWFWVGGRELSPEGITCCCSLIPSGAEWARVSAVNATSWEPLTNLS   313

Query   308  LVCLAPESAPCDVGVSSADGSPGIKVTWKQGTRKPLEYVVDWAQDGDSLDKLNWTRLPPG   367
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            LVCL   SAP V VSS GS  + VTW+ G  +PLE+VVDWA+DGD L+KLNW RLPPG
Sbjct  314  LVCLDSASAPRSVAVSSIAGSTELLVTWQPGPGEPLEHVVDWARDGDPLEKLNWVRLPPG  373

Query  368  NLSTLLPGEFKGGVPYRITVTAVYSGGLAAAPSVWGFREELVPLAGPAVWRLPDDPPGTP  427
            NLS LLPG F  GVPYRITVTAV + GLA+A SVWGFREEL PL GP +WRL D PPGTP
Sbjct  374  NLSALLPGNFTVGVPYRITVTAVSASGLASASSVWGFREELAPLVGPTLWRLQDAPPGTP  433

Query  428  VVAWGEVPRHQLRGQATHYTFCIQSRGLSTVCRNVSSQTQTATLPNLHSGSFKLWVTVST  487
             +AWGEVPRHQLRG  THYT C QS   +VC NVS  TQ+ TLP+L G  +LWVT ST
Sbjct  434  AIAWGEVPRHQLRGHLTHYTLCAQSGTSPSVCMNVSGNTQSVTLPDLPWGPCELWVTAST  493

Query  488  VAGQGPPGPDLSLHLPDNRIRWKALPWFLSLWGLLLMGCGLSLASTRCLQARCLHWRHKL  547
            +AGQGPPGP L LHLPDN +RWK LP  L LWGL L+GCGLSLA++      RC H RHK+
Sbjct  494  IAGQGPPGPILRLHLPDNTLRWKVLPGILFLWGLFLLGCGLSLATS----GRCYHLRHKV  549

Query  548  LPQWIWERVPDPANSNSGQPYIKEVSLPQPPKDGPILEVEEVELQPVVES---PKASAPI  604
            LP+W+WE+VPDPANS+SGQP++++V   QP  D PILEVEE+E  PV+ES      +A+AP+
Sbjct  550  LPRWVWEKVPDPANSSSGQPHMEQVPEAQPLGDLPILEVEEMEPPPVMESSQPAQATAPL  609

Query  605  YSGYEKHFLPTPEELGLL  622
               SGYEKHFLPTPEELGLL
Sbjct  610  DSGYEKHFLPTPEELGLL  627
```

```
CPU time:       0.04 user secs.        0.00 sys. secs        0.04 total secs.

Lambda      K       H
   0.317    0.135    0.450

Gapped
Lambda      K       H
   0.267   0.0410     0.140


Matrix: BLOSUM62
Gap Penalties: Existence: 11, Extension: 1
Number of Sequences: 1
Number of Hits to DB: 4813
Number of extensions: 2613
Number of successful extensions: 4
Number of sequences better than 10.0: 1
Number of HSP's gapped: 1
Number of HSP's successfully gapped: 1
Length of query: 623
Length of database: 1,634,373,987
Length adjustment: 142
Effective length of query: 481
Effective length of database: 1,634,373,845
Effective search space: 786133819445
Effective search space used: 786133819445
Neighboring words threshold: 9
X1: 16 ( 7.3 bits)
X2: 129 (49.7 bits)
X3: 129 (49.7 bits)
S1: 41 (21.6 bits)
S2: 82 (36.2 bits)
```